

# Suction Regulators

## Boehringer Platinum Series Suction Regulator Recommendations for Cleaning and Reprocessing



**BOEHRINGER**®

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# Introduction

These recommendations are for processing Boehringer Platinum Series Suction Regulators sold directly from Boehringer Laboratories, LLC. These recommendations have been validated and are in accordance with:

1. ANSI/AAMI ST81:2004 – Sterilization of medical devices-Information to be provided by the manufacturer for the processing of resterilizable medical devices.
2. AAMI TIR 12:2004 – Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities. A guide for device manufacturers 1<sup>st</sup> ed.
3. AAMI ST77:2006 – Containment devices for reusable medical device sterilization.
4. ISO 14937:2000 – Sterilization of health care products – General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization product.

## Scope

### MODELS

This document contains recommended instructions for the safe care, handling and processing of the 3800 series of Boehringer Platinum Suction Regulators, produced starting January 2011. This instruction sheet is an addendum to, and not a replacement for the complete instructions for use for your suction regulator. Please refer [www.boehringerlabs.com](http://www.boehringerlabs.com) or call 1-800-642-4945 for more information.

### CLEANING

The cleaning protocols described herein are intended to be used on suction regulators that have been grossly contaminated. Devices that show no signs of gross fluid intrusion may not require cleaning and may have sufficiently low bio-burden such that they may only require processing through an autoclave. It is the responsibility of the hospital to determine whether or not gross decontamination is required<sup>1</sup>, see page 5 for inspection instructions. Cleaning equipment should be qualified and validated by the hospital to ensure suitability for its intended purpose.

### PROCESSING

Processing via steam sterilization is recommended to ensure patient and staff safety. The instructions contained herein describe methods by which, Boehringer Platinum Series Suction Regulators can be processed. It is the responsibility of the hospital to ensure that any devices subjected to these guidelines have been appropriately processed and that the sterilization equipment is qualified and validated to ensure its suitability for this purpose.

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<sup>1</sup> Gross contamination of suction equipment is an extraordinary event. Normal precautions such as the appropriate use of collection canisters, gravity trap bottles, and hydrophobic filters reduce, but do not eliminate the probability of such events.

# Terminology

<b>CAUTION</b>	Alerts user to actions or conditions that can cause damage to the device or may result in substandard performance of the device or system.
<b>CLEANING</b>	Removal of contamination from an item to the extent necessary for further processing or for intended use
<b>CONTAMINATED</b>	State of having been actually or potentially in contact with microorganisms
<b>IMPORTANT</b>	Indicates an action that is emphasized to ensure proper operation of equipment
<b>MANUAL CLEANING</b>	Cleaning without the use of a washer or washer-disinfector
<b>PROCESS(ING) (REPROCESSING)</b>	Act of subjecting medical devices to the various routes used for disinfection and sterilization
<b>STERILIZATION</b>	A validated process used to render a device free from all forms of viable microorganisms
<b>WARNING</b>	Alerts user to actions or conditions that could result in injury to user or patient

## Safety Information

### WARNING!

- Boehringer suction regulators are intended to be cared for per the instructions in this manual as well as the instructions for use specific to each model of suction control. Failure to follow the guidelines herein may result in unsatisfactory levels of disinfection or sterilization and may compromise regulator performance.
- Suction regulators are used in a clinical setting on a variety of patients. The mechanisms that allow the regulators to function may contain biological contamination even though there are no apparent signs of contamination. Always utilize appropriate PPE when handling suction controls that have been in clinical use.
- Failure to ensure that the suction regulator is functioning properly after processing can increase patient risk. Ensure that suction controls function properly before they are returned to service.

### CAUTION!

- Hydrophobic filters, gravity shut offs, and gravity safety traps provide a barrier to gross biological contamination but do not prevent microbiological pathogens from entering the suction regulator. Be mindful that these measures alone do not ensure a pathogen free device will be returned to clinical service.
- Avoid solutions containing high chlorine content (>1%) as this may cause irreversible damage to the suction regulator components.
- Devices that are visually contaminated must be thoroughly cleaned before processing to ensure the efficacy of the autoclave process.
- Flash sterilization is not a recommended process for Boehringer Suction Regulators

## LIMITS ON REPROCESSING

- All detergents used should have a neutral pH
- Repeated manual washing and autoclaving cycles as described herein should have minimal effects on the fitness for use of Boehringer Platinum Series Suction Regulators that were made starting January, 2011.

## Considerations

- The end user / individual / department responsible for processing these devices should comply with local laws and ordinances in countries where reprocessing requirements are more stringent than those detailed in this manual.
- Suction regulators are generally not considered sterile instruments and are not typically stored in sterile containers before use. Healthcare Systems are responsible for determining an appropriate protocol for the scheduling of suction regulator processing.
- The use of personal protective equipment is recommended whenever handling a potentially contaminated piece of medical equipment.
- It is the hospitals responsibility to ensure that personnel have proper qualifications and are trained to perform sterile reprocessing.
- Equipment used for reprocessing should be validated and routinely monitored to ensure proper performance.
- Any deviation outside of these processing protocols should be properly evaluated for efficacy and potential adverse consequences.
- It is the responsibility of the hospital to ensure that suction regulators have been appropriately processed.

## Reprocessing Instructions

### POINT OF USE CARE

- Wipe all exterior surfaces of the suction regulator with a surface disinfectant per manufacturer's instructions. Appropriate disinfectants are:
  - 3M Quat®
  - Cavacide®
  - 1:10 bleach solution (wipe, but do not soak in bleach) followed by a 70% ETOH wash
- Soiled and potentially contaminated suction regulators should be transported separate from non-contaminated devices, in a container that minimizes the potential to spread contamination
- Suction Regulators should be sent for processing as soon as possible if gross contamination is evident.

## PREPARATION BEFORE CLEANING

### Initial Assessment

- To determine whether or not the unit has been grossly contaminated, loosen the set screw (2 turns max) on the control knob with a 1/16<sup>th</sup> Allen key.



- Remove the adjustment knob (refer to the user manual for more detailed instructions).

- Visually inspect the piston/stem assembly for signs of gross contamination.



- If the unit shows no visible contamination, reattach the adjustment knob prior to processing.
- If visible contaminants are present, the unit requires complete disassembly and gross decontamination (refer to the device's user manual for detailed instruction on disassembling the suction regulator).

## MANUAL CLEANING

- After the suction regulator is fully disassembled, all regulator components should soak for a minimum of 10 minutes in a solution of warm water and pH neutral detergent such as MetriZyne<sup>®</sup>. Refer to the detergent manufacturer's instructions for concentration recommendation.
- After soaking, thoroughly rinse components with warm tap water.
- Regulator components should be placed in a fresh solution of warm tap water and pH neutral detergent such as MetriZyne<sup>®</sup> and scrubbed with a soft bristle brush to remove deposits. Refer to the detergent manufacturer's instructions for concentration recommendation.
- The components should then be removed from the solution and rinsed with warm tap water.
- Components should be placed in an ultrasonic cleaner, completely submerged for a minimum of 10 minutes.
- Rinse components thoroughly with warm tap water.

- Inspect regulator components for visible soil. Repeat cleaning process again if visible soil is observed.
- Ensure that components are dry before reassembling the suction control. If using an automatic dryer, ensure that the temperature does not exceed 132°C (270°F).

## STEAM STERILIZATION

- Ensure that all suction regulators are properly assembled and the control knobs are turned to the ON or CONT. mode. Refer to each model’s instructions for use for guidance with proper assembly.
- Ensure that the adjustment knob is turned counterclockwise until it stops to keep the internal passageways as open as possible.
- Suction regulators can be packaged in a variety of ways for processing including a peel pouch, sterilization wrappers or instrument tray.
- The following are recommendations for sterilizing Boehringer Suction Controls

Cycle Type	Minimum Sterilization Exposure Time (min)	Minimum Sterilization Exposure Temperature	Minimum Dry Time*
Prevacuum	4	132° C (270°F)	20 Minutes

\*Dry times will vary depending upon a number of factors including packaging materials, environmental conditions, steam quality, regulator mass and sterilizer specification (cool down time and performance). The processor should visually inspect the regulator for signs of moisture.

## VERIFICATION OF PERFORMANCE

- After Boehringer suction controls are processed, it is imperative that they be checked for basic function before returning into service. Please refer to each specific model’s instructions for use for proper methods to check regulator performance.
- At a minimum check the following functions:
  - The regulator can maintain a constant level of vacuum
  - The gauge properly indicates the vacuum level
  - The regulator functions in all operating modes (eg. Continuous, intermittent and line)
  - The regulator flow rate is in compliance with the model’s specifications
- If you have questions at any time, please feel free to contact Boehringer at 1-800-942-4945.

## Appendix A: Understanding Boehringer’s Position on Suction Regulator Processing

In the mid 1960s Dr. Earl Spaulding, Chair of Microbiology and Immunology from 1949 to 1972 at Temple University’s School of Medicine, created a system to identify a patient’s risk for infection from medical instruments. This system was simple to understand and is widely accepted in the U.S. and repeatedly cited by the CDC. Infectious disease doctors and Sterile Processing Departments understand the implications of Spaulding. This system is a guide to assist hospital personnel in identifying the proper cleaning, disinfection and sterilization requirements for all of their equipment. Spaulding does not call out which equipment falls into which category, but rather based on the risk of the instrument and where it is used will dictate its classification in this scheme.

The Spaulding Classification states the following

Classification	Noncritical Equipment	Semi-critical Equipment	Critical Equipment
<b>Definition</b>	Equipment that touches only intact skin and not mucous membranes, or does not directly touch the client/patient/resident	Equipment that comes in contact with non-intact skin or mucous membranes but do not penetrate them	Equipment that enters sterile tissues including the vascular system
<b>Equipment Examples</b>	Environmental Surfaces, Stethoscopes, BP Cuffs, Baby scales	Laryngoscopes, Anesthesia Equipment, Fingernail Care, <b>Suction Regulators,</b>	Surgical Instruments, Endoscopes, Foot Care Equipment, Eye Equipment
<b>Level of Processing Required</b>	Cleaning followed by <b>low level disinfection</b> . In some cases, cleaning alone is acceptable	Cleaning followed by <b>high level disinfection (HLD)</b> at a minimum. <b>Sterilization is preferred</b>	Cleaning followed by <b>sterilization</b>
<b>Effectiveness of Cleaning</b>	Low Level Disinfection kills most vegetative bacteria, some fungi and some viruses. <b>DOES NOT KILL MYCOBACTERIA OR SPORES.</b>	High Level Disinfection destroys vegetative bacteria, mycobacterium, fungi and most viruses. <b>DOES NOT KILL SPORES.</b>	Sterilization destroys all forms of microbial life including bacteria, viruses, spores and fungi
<b>Sample Processing Products</b>	Soak for 10 minutes in 3% Hydrogen Peroxide, 60-95% Alcohol or Quaternary disinfectant	Soak for 20 minutes in 2% glutaraldehyde, 6% Hydrogen peroxide or Cidex OPA	Steam autoclaving is the most commonly used method; however, sterilization with hydrogen peroxide (Sterrad), ETO or Peracetic acid (STERIS) is also accepted.

Traditionally, people would have placed suction regulators into a ‘Non-Critical ‘category. In this category the only required cleaning and processing would be to wipe down the outside of the unit. The internal lumens of the regulator would not be touched and would remain contaminated between patients.

The fact that intermitting regulators connect directly with the mucous membranes of the stomach, and that there is a demonstrated risk from the contaminants in the regulator, suggests that these instruments are considered for inclusion into the Semi-Critical Classification. As a result of being included in this classification, suction regulators require at a minimum, a high level disinfection, preferably sterilization.



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***A free trial evaluation  
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(800) 642-4945 or 610-278-0900.***